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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/644,325	08/19/2003	Hans Weiher	VOS-44 CON	6657

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EXAMINER	
HARLE, JENNIFER I	

ART UNIT	PAPER NUMBER
1654	

DATE MAILED: 03/02/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/644,325	WEIHER ET AL.	
	Examiner	Art Unit	
	Jennifer I. Harle	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 December 2004*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-10* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-10* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

In light of Applicant's Amendment the previous Election/Restriction is withdrawn and the new Election/Restriction is implemented.

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

   I. Claims 1-2 and 9-10 (as it pertains to chronic renal disease), 3-4, and 8, drawn to a method of treating degenerative chronic renal disease that is ROS induced by inhibiting the gamma-GT activity in a subject, classified in various classes and subclasses.

   II. Claims 1-2 and 9-10 (as it pertains to degenerative chronic inner ear condition or injury) and 5-7, drawn to a method of treating degenerative chronic inner ear condition or injury by inhibiting gamma-GT activity in a subject, classified in various classes and subclasses.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions I-II are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different methods of use are unrelated if one of three differences are found between them. These differences are 1) the population being treated 2) the material being used 3) the methodology for treatment. If any one or more of these difference exist and are patentably distinct, then the methods are unrelated. In the instant case the different methods of use are unrelated because the patient populations treated for each method is divergent, i.e. a patient with a chronic renal

disease, i.e. diabetic nephropathy has diabetes, while a patient sensineural deafness induced by age, has an inner ear problem that is age related and not related to diabetes.

3. Furthermore, searching the inventions of Group I and Group II would impose a serious search burden. The inventions require technical literature searches for the different categories of diseases that are not coextensive, e.g. the databases and terminology and synonyms to search for chronic renal diseases vs. inner ear degenerative conditions or injury are not coextensive in the prior art.

4. Applicant is also required to select a specific inhibitor for either Group I or Group II.

5. As the invention is drawn to thousands of different inhibitors, which vary distinctly in their structures and functions as the pharmaceutical itself or an intermediate in the preparation of a compound, i.e. an isoxazoleacetic acid (nitrogen and oxygen ring containing compound) and its derivatives (resulting in an unlimited number of compounds as derivatives allow for substitutions, deletions and additions in any place in the compound and thus would potentially result in a lack of a known core), a butanoic acid (alkyl chain containing compound with boron) and its derivatives (resulting in an unlimited number of compounds as derivatives allow for substitutions, deletions and additions in any place in the compound and thus would potentially result in a lack of a known core), amino acids and peptides containing three component in the general formula only one of which is constant and the others are totally unknown and can be oligopeptides and polypeptides of unknown length and amino acids (i.e. natural and unnatural with multiple side chains, cyclics, etc.) (resulting in a total lack of a known core of the compound), peptidomimetic glutathione analogues that is a compound containing non-peptidic structural elements that are capable of mimicking or antagonizing the biological action(s) of

natural parent peptides and no longer have classical peptide characteristics such as enzymatically scissile peptidic bonds, moreover, it is generally accepted that they comprise fragments and may be modified or substituted (thus they would read on a plethora of compounds which would not be required to have a common core with each other let alone any of the other groups and are not disclosed as being required to do so)[1] and anilides which are any compound containing the univalent group C_6H_5NH–, derived from aniline, as acetanilide, C_8H_9NO and thus can encompass any thing that is attached to this group that would be utilized to prepare a pharmaceutical preparation.

6. Searching each of these compounds in conjunction with either method would impose a serious search burden for the examiner. These compounds/peptides/peptidomimetics are not required to have any specific core structure and can vary greatly within each of the groups themselves. The inventions may have a separate status in the art via their potential to have separate classifications, may require structure searches, in cases where descriptive information is required non-patent technical databases will need to be searched and cross-referenced. Chemical compounds may not be concommitant with peptides and peptidomimetic analogues may not concomitant with the peptides nor will the different compounds be concomitant within the same journal articles or patents. Deriviatives of each of the compounds can vary completely and thus the searching is not coextensive between a compound and its derivative. Thus, an individual search is required of each individual compound. **Applicant is required to select a specific inhibitor**, to which, the elected invention will be examined on the merits as drawn to; as well as identifying those claims to which the selected composition reads. This requirement is not to be

[1] Glossary of Medical Terms Used in Chemistry (IUPAC Recommendations 1998), I to X, 1998,

taken as an election of species, but rather as a selection of a single invention, since each compound is assumed to be a patentable distinct invention, in the absence of evidence to the contrary.

7. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined event though the requirement be traversed (37 CFR 1.143).

8. This application contains claims directed to the following patentably distinct species of the claimed invention:

Group I: Specific Chronic Renal Diseases, i.e. focal glomerulosclerosis, segmental glomerulsclerosis, minimal change nephrosis, inflammatory glomerulopaties, diabetic nephropathy, autoimmune glomerulopathies; and

Group II: Specific Inner Ear Degenerative Diseases: i.e., sensineural deafness induced by age, physiological status metabolic status, induced by specific drugs – aminoglycosides, cisplatin derivatives, otosclerosis.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

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http://www.chem.qmul.ac.uk/iupac/medchem/ix.html, printed October 4, 2004, pp. 1-7; and Barton, et al. US

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

9. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer I. Harle whose telephone number is (571) 272-2763. The examiner can normally be reached on Monday through Thursday, 6:30 am to 5:00 pm,.

11. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on (571) 272-0974. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

6,071,707.

12. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Jennifer I. Harle
Examiner
Art Unit 1654

March 1, 2005